K102699

APR - 1 2011

Admin 3.0
510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

Judith Wallach, Regulatory Affairs Administrator
Regulatory Affairs
Abbott Laboratories Diagnostics Division
Dept. 9V6 AP6C-2
100 Abbott Park Road
Abbott Park, IL 60064

Device Name:

Reagent Kit:
Classification Name: Gentamicin test system
Trade Name: ARCHITECT *i*Gentamicin
Common Name: Gentamicin
Governing Regulation: 862.3450
Device Classification: Class II
Classification Panel: Clinical Toxicology
Code: LCD

ARCHITECT *i*Gentamicin Calibrator Kit
Classification Name: Calibrators, Drug Specific
Trade Name: ARCHITECT *i*Gentamicin Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.3200
Device Classification: Class II
Classification Panel: Clinical Toxicology
Code: DLJ

Legally marketed device to which equivalency is claimed:

AxSYM Gentamicin (K935376)

Intended Use of Device:

The ARCHITECT *i*Gentamicin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.

Description of Device:

The ARCHITECT *i*Gentamicin assay is a one-step immunoassay for the quantitative determination of gentamicin in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.
In the ARCHITECT *i*Gentamicin assay, sample, anti-gentamicin coated paramagnetic microparticles, and gentamicin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-gentamicin coated microparticles bind to the gentamicin present in the sample and to the acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of gentamicin in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:

The ARCHITECT *i*Gentamicin assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of gentamicin in human serum or plasma. The AxSYM Gentamicin assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology for the quantitative measurement of gentamicin in serum or plasma.

Summary of Analytical Performance:

The ARCHITECT *i*Gentamicin assay is substantially equivalent to the AxSYM Gentamicin assay in terms of analytical performance data in this 510(k) submission.

The analytical performance of the ARCHITECT *i*Gentamicin assay was demonstrated through the following studies, which are provided in this 510(k) submission:

- Precision
- Limit of Blank, Limit of Detection, and Limit of Quantitation (Sensitivity)
- Linearity
- Interferences
- Recovery
- Manual Dilution
- Matrix Comparison (Tube Type)
- Method Comparison (Correlation)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
c/o Judith Wallach, RAC
Sr. Regulatory Administrator
ADD Regulatory Affairs
Dept 09V6, Bldg. AP6C-2
Abbott Park, IL 60064-6095

Re: k102699
Trade Name: ARCHITECT iGentamicin, ARCHITECT iGentamicin Calibrators (A-F)
Regulation Number: 21 CFR 862.3450
Regulation Name: Gentamicin Test System
Regulatory Class: Class II
Product Codes: DLJ, LCD
Dated: February 16, 2011
Received: February 17, 2011

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Dear Ms. Wallach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Admin 5.0
Indications for Use

510(k) Number (if known):

Device Name: ARCHITECT *i*Gentamicin

Indications for Use:

Reagents:

The ARCHITECT *i*Gentamicin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.

Calibrators:

The ARCHITECT *i*Gentamicin Calibrators are for the calibration of the ARCHITECT *i* System with *STAT* protocol capability when used for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102699